Human Immunodeficiency Virus (HIV) &
Hepatitis C Virus (HCV)
Outbreak Response Plan

January 2018
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Situation Overview
In early 2015, the Indiana Department of Health noticed a cluster of eleven HIV cases in a county that had historically observed less than one new case of HIV each year. The majority of these cases were among persons who inject drugs (PWID) who had shared needles while injecting the prescription opioid Opana\(^1\).

Eventually, the outbreak grew to more than 180 cases, with almost all cases co-infected with HCV. It is estimated the lifelong medical costs attributed to this outbreak will cost the state of Indiana over 80 million dollars\(^2\).

The Centers for Disease Control and Prevention (CDC) recently deemed 41 Tennessee counties, home to about 20% of the state’s population, at-risk for the rapid dissemination of HIV and HCV among PWID similar to what happened in Indiana\(^3\).

Purpose
This plan establishes a framework for the Tennessee Department of Health (TDH) to prepare for and respond to an outbreak of HIV and HCV in Tennessee.

The plan and its supporting documentation:

- Describe routine surveillance efforts
- Outline roles and responsibilities for: (1) enhanced surveillance, (2) identification of a cluster of cases, and (3) declaration of an outbreak
- Provide informational resources for clinicians, public health staff, and those receiving testing

A cluster is defined as any area of suspicion under investigation prior to determining the occurrence of an outbreak of HIV and/or HCV transmission. Clusters are identified through routine surveillance, enhanced surveillance, and/or regional communication.

\(^1\) [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6416a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6416a4.htm)

\(^2\) [http://www.publichealth.indiana.edu/features/2015_WAD.shtml](http://www.publichealth.indiana.edu/features/2015_WAD.shtml)

**HIV in Tennessee**

In Tennessee, diagnoses of HIV infection (i.e., HIV cases) are reportable by providers and laboratories\(^4\)\(^5\).

In 2016, 714 Tennesseans were newly diagnosed with HIV, and as of December 31, 2016, 17,489 people were known to be living with HIV (data accessed from the Tennessee Enhanced HIV/AIDS Reporting System (eHARS) on June 30, 2017). Additionally, there were 304 deaths in 2015 among persons living with diagnosed HIV (data accessed from eHARS on June 30, 2017).

New diagnoses of HIV infection and deaths from HIV/AIDS have gradually decreased over the past five years. These decreases are attributed to a number of factors, including the availability of antiretroviral medications through the Ryan White Part B Program, behavioral interventions performed by our HIV Prevention Program, Partner Services (PS) activities conducted through our STD Program, and vast improvements in the timeliness and availability of HIV laboratory data from our Surveillance Program.

Disparities by gender, race/ethnicity, age, HIV transmission risk, and geography contribute to the distribution of new HIV diagnoses, people living with diagnosed HIV infection, and health care outcomes among people living with HIV in Tennessee. In 2016, individuals diagnosed in Tennessee were predominantly young black men who have sex with men (MSM). Further, 6% of the new HIV diagnoses self-reported injection drug use and, of these, 46% were also MSM.

As Figure 1 shows, the newly diagnosed HIV case rate in Tennessee for 2016 was 11.0 cases per 100,000 persons. Darker shaded areas bear a higher burden of HIV cases based on the population within that specific county.

Figure 2 depicts the burden of HIV within Tennessee counties based on the current address of a living person with HIV/AIDS as of December 31, 2016 (269.1 per 100,000 persons statewide). For both new and living cases, the areas most affected by HIV cases include the metropolitan areas of Memphis, Nashville, and Chattanooga, as well as neighboring counties.

Figure 1: Case Rates of Persons with Newly Diagnosed HIV Infection in Tennessee by County – 2016

Figure 2: Case Rates of Persons Living with Diagnosed HIV Infection in Tennessee by County – 2016
**HCV in Tennessee**

In Tennessee, acute HCV cases are reportable by providers and laboratories, while chronic cases of HCV are reportable by laboratory only\(^6\),\(^7\).

In March 2015, the Viral Hepatitis (VH) Section was incorporated into the HIV/STD program. At that time, VH surveillance efforts were expanded and the process for data collection and entry of HCV laboratory reports was streamlined. Beginning in July 2015, chronic HCV paper laboratory reports have been sent by the regions to TDH Central Office for data entry and creation of investigations, utilizing with CDC/CSTE case definitions. As of March 30, 2016, each public health region received in-person training by VH Surveillance staff. AVH user guide was developed to facilitate this effort and is available upon request.

As data collection continues to improve, reported cases of acute and chronic HCV will become more reflective of the true burden of disease in Tennessee. Although there have been no outbreaks of acute HCV in Tennessee, the eastern part of the state is disproportionately affected by both acute and chronic HCV.

As **Figure 3** shows, the newly diagnosed acute HCV case rate in Tennessee for 2016 was 3.7 cases per 100,000 persons. Darker shaded areas bear a higher burden of HCV cases based on the population within that specific county.

**Figure 4** depicts the burden of newly reported chronic HCV within the Tennessee public health regions in 2016 (272.9 per 100,000 persons statewide).

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Figure 3: Case Rates of Reported Acute Hepatitis C in Tennessee by County - 2016

Figure 4: Case Rates of Newly Reported Chronic Hepatitis C Cases in Tennessee by County – 2016
**Routine Surveillance**
TDH’s HIV and VH Surveillance Programs systematically collect, analyze, interpret, and disseminate data to characterize trends in infection, detect active transmission, implement public health interventions, and evaluate public health response. HIV, acute HCV, and chronic HCV are nationally notifiable conditions and are reported to CDC. All cases of newly diagnosed HIV or acute HCV must have a field investigation, while chronic HCV does not require a field investigation. Field investigations include an interview with the patient to assess ongoing risk factor(s), risk reduction messaging, and elicit additional PS information. On an ongoing basis, Central Office epidemiologists work closely with regional health departments to support data collection and entry into the appropriate surveillance systems.

**HIV Routine Surveillance**
Tennessee’s Enhanced HIV/AIDS Reporting System (eHARS) is a browser-based application provided by CDC. TDH’s HIV Surveillance Program uses eHARS to collect and monitor information on individuals who are newly diagnosed or living with HIV. All newly diagnosed cases of HIV must have a field investigation.

**HCV Routine Surveillance**
HCV data are housed in the National Electronic Disease Surveillance System (NEDSS) Based System (NBS) provided by CDC. TDH’s VH Surveillance Program uses NBS to collect and monitor information for individuals with acute and/or chronic HCV, as well as all other reportable conditions excluding HIV, Gonorrhea, Chlamydia, and Syphilis.

On January 1, 2017 chronic HCV was added as a reportable disease for laboratories only and passive surveillance is conducted at the Central Office. Prior to this, cases of chronic HCV were identified based on information received when classifying suspected acute infections (e.g. received laboratory results).

**Enhanced Surveillance**

**HIV Enhanced Surveillance**
Reportable HIV data are extracted from eHARS to provide situational awareness reports, by public health region, on a weekly and monthly basis. Monitoring and evaluation of HIV surveillance includes weekly temporal cluster analyses using traditional algorithms for aberration detection, monthly threshold reports, and review of risk factor information.

**Weekly Analysis of Newly Reported Cases by Public Health Region** - Using data from eHARS, a report is generated each Monday to identify newly reported cases of HIV by public health region. If a higher than expected number of cases is reported in a public health region (e.g., comparison to the monthly mean over the prior 18-months), additional analyses at the region (and potentially county-level) are conducted by a TDH Central Office epidemiologist. This analysis will determine if the individuals reported meet the surveillance case definition for HIV and to further ascertain risk factor information.

**Monthly Analysis of Newly Reported Cases Across the State and by Program-identified Regions** - Two weeks after the end of each month, a threshold report is generated by a Central...
Office epidemiologist to examine the number of new HIV cases in Tennessee, overall and by public health region. The report is distributed to and monitored by HIV/STD supervisors in the Metro Health Departments, Public Health Regional Offices, the STD Prevention Program Director, and the HIV Surveillance Director. This report indicates if the number of HIV diagnoses is in the range of what is expected, or if the number is higher than expected at either a “warning” level or at a “rapid response” level. A warning level is indicated when the number of new cases is equal to the mean number of new cases for the past eighteen months plus one standard deviation. If the number of new cases is equal to the mean number of new cases of the past eighteen months plus two standard deviations, a rapid response is indicated. Additionally, the number of new cases for each of the last three months is used for monitoring trends.

If a warning or rapid response level is detected, a Central Office epidemiologist will complete analyses at the county level, including verifying that cases are new Tennessee HIV cases, examining risk factor information, reviewing the county and facility of diagnosis, and accessing PRISM to determine if the cases are connected through a shared partner(s) and, if they are, monitoring partner outcomes. If a cluster is identified, the response team will assemble and follow the procedures outlined in this document. The Medical Director will determine when to notify leadership of the cluster, and potential outbreak.

**Monthly Analysis of Risk Factors of Reported Cases** - On a monthly basis, a report is prepared to examine cases reported among IDU and MSM/IDU during the last three years, by county. If the number of cases in the current year is high compared to previous years or a county only has a case identified in the current year, a Central Office epidemiologist and regional field staff will investigate to determine if there is a potential cluster. If a cluster is identified, the response team will assemble and follow the procedures outlined in this document. The Medical Director will determine when to notify leadership of the cluster, and potential outbreak.

**HCV Enhanced Surveillance**

The Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE) is used for acute HCV (probable and confirmed case status) to provide situational awareness. Reportable HCV disease data are extracted from the primary reportable disease surveillance system, NBS, in CSV format and are transferred to ESSENCE by secure file transfer protocol using a daily, scheduled SAS program. MyESSENCE was used to build a situational awareness dashboard for HCV surveillance staff. These dashboards were developed to display reports statewide and in the 24 eastern counties of the state where HCV prevalence is highest.

The HCV dashboard includes daily and weekly temporal cluster analyses using traditional algorithms for aberration detection, spatial cluster analysis using zip code, and a line list of open investigations. The HCV dashboard facilitates simple record-level investigation of cases or clusters and allows for the rapid quantification of demographic variables in detected clusters. Situational awareness dashboards allow for timely and responsive monitoring of acute HCV temporal and spatial trends—functionality not available in NBS. Visualizations and basic demographics are accessible in one application allows real-time sharing of information with public health staff. ESSENCE’s ability to identify aberrations allows staff to easily investigate and describe clusters of cases and quickly determine if additional follow up is warranted.
Daily Analysis of Temporal/Spatial Aberrations of Reported Cases - One of the viral hepatitis epidemiologists examines MyESSENCE each day for any aberrations (warning or alert). If an aberration is detected, a line listing is produced and temporal and spatial trends are examined. Each case is looked up in NBS to examine supplemental information (i.e. comments) within each investigation that are not visible within MyESSENCE. Once any potential clusters are ruled out (based on location, age, and risk factors), risk factors are examined closely for any potential HAI infection. If a client indicates they have no self-reported risk factors but had a medical procedure involving blood, the case is sent to HAI for further investigation. If the patient has a sexual or needle sharing contact and also indicates a medical procedure involving blood, and an epidemiological risk factor to the sexual or needle sharing partner is not available, the HCV epidemiologist will contact the regional field staff for further follow-up.

All aberrations, and their outcomes, are tracked on a de-identified Microsoft Excel spreadsheet and kept on the VH shared drive. This allows the VH epidemiologists to communicate to each other with regard to which cases/aberrations have been thoroughly examined.
Assignment of Responsibilities

Responsibilities: Investigation of a Cluster
HIV/HCV clusters will be identified by the TDH HIV or VH Surveillance Programs or at the regional/local health department level. The decision to declare an outbreak will be made by program leadership and will be informed by the findings from the cluster investigation.

Responsibilities that will be followed in the event of a cluster investigation are outlined below:

**HIV Surveillance & Epidemiology Program and VH Program Directors**
- Document Timeline of Events, including start date of investigation
- Notify CEDEP leadership and other stakeholders, as appropriate
- Provide regional leadership with copies of the following:
  - Outbreak Response Plan
  - Outbreak Response Questionnaire (Appendix E)
  - Situation Analysis Report
  - JIT Trainings for HIV and HCV Testing
  - Laboratory Specimen and Collection Transport Guidance (Appendix D)
- Grant REDCap database access to regional epidemiologist(s)
- Determine Central Office and Regional ICS
- Determine Regional/Metro and Central Office call schedule; provide Situation Report Template (Appendix F); determine if additional staffing resources needed/deploy
- Determine which laboratory tests will need to be run; review/update specimen collection and transport guidelines with state laboratory and regional staff; appoint Central Office staff member to communicate real-time laboratory results to region via secure Excel spreadsheet

**HIV Epidemiology Lead**
- Complete Cluster Investigation Template for HIV (Appendix A)
- Compile epidemiology curve for HIV data
- Compile ongoing line list of cases and contacts for HIV data
  - Provide STATENOs to VH Surveillance for HCV co-infection analysis
  - Provide STATENOs to STD Prevention for PRISM partner and risk factor ascertainment
- Manage outbreak response questionnaire and subsequent REDCap data entry
- Initiate Social Network Analysis
- Perform ongoing data reconciliation: REDCap to eHARS

**VH Surveillance Director**
- Complete Cluster Investigation Template for HCV (Appendix A)
- Compile epidemiology curve for HCV data
- Compile ongoing line list of cases and contacts for HCV data
- Identify HIV/HCV co-infections
- Perform Accurint searches, as requested
• Appoint dedicated staff to immunization registry to determine Hepatitis A and Hepatitis B vaccination Status
• Perform ongoing data reconciliation: REDCap to NBS

STD Epidemiology Lead
• Compile ongoing line list of partner and risk factor information from PRISM for HIV cases and contacts
• Perform ongoing data reconciliation: REDCap to PRISM
Responsibilities: Declaration of an Outbreak
Upon declaration of an outbreak, the Central Office response will be organized in the following incident command structure (to be adjusted as needed based on situational needs). Local/Regional leadership and Central Office leadership will discuss and determine (at the time of the incident) whether to operate within a joint/unified command structure, or if separate parallel command structures (with liaisons from each agency embedded each other’s command structure) will be activated. Local/Regional Leadership will need to determine an incident command structure and communicate that to Central Office Leadership.

Proposed Incident Command Structure
**Immediate and Ongoing Actions Upon Declaration of an Outbreak**

The tasks below provide a framework for immediate actions once a cluster has been investigated and an outbreak has been declared. In addition to the below, cluster activities continue throughout the response (see ‘Responsibilities: Investigation of a Cluster’).

<table>
<thead>
<tr>
<th>Task</th>
<th>Responsible Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify Central Office Liaison to Serve in the Regional Health Operations Center and Provide Updates to Central Office staff</td>
<td>Local/Regional Health Department Leadership/DACO</td>
</tr>
<tr>
<td>Activation of Public Hotline and Development of REDCap Database to Track Call Volume and Nature</td>
<td>PIO/Communications/External Guidance Development (Planning Section)</td>
</tr>
<tr>
<td>Outreach to Area Providers with “what to look for, and who to call” Type Message via Local Networks and Medscape</td>
<td>External Guidance Development (Planning Section)</td>
</tr>
<tr>
<td>Coordinate Communication with CDC</td>
<td>Central Office DACO</td>
</tr>
<tr>
<td>Respond to Local Media Inquiries</td>
<td>Local/Regional PIO (with Central Office support)</td>
</tr>
<tr>
<td>Inform and Collaborate with Local CBO(s) and Syringe Service Programs to Facilitate Outreach and Decrease risk of Transmission (i.e. PrEP, clean needles/syringes, treatment, etc.)</td>
<td>Local/Regional Health Department Leadership/DACO/Operations</td>
</tr>
</tbody>
</table>
Appendices

Appendix A – Cluster Investigation Template

HIV Cluster Investigation

**Jurisdictions (Counties):** MidCumberland (Williamson), Nashville

**Cases:** 4

**Contacts Under investigation:** 2

**Notes:** Additional contacts anticipated

### Laboratory Confirmed Cases

Contacts = sexual partners or needle-sharing partners

<table>
<thead>
<tr>
<th>County</th>
<th>STATENO</th>
<th>Initials</th>
<th>Sex</th>
<th>Age</th>
<th>HIV Positive?</th>
<th>HIV Diagnosis Date</th>
<th>HCV Positive?</th>
<th>IDU?</th>
<th># Named Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davidson</td>
<td>00001</td>
<td>AS</td>
<td>M</td>
<td>19</td>
<td>Y</td>
<td>10/01/16</td>
<td>Y</td>
<td>Y</td>
<td>3</td>
</tr>
<tr>
<td>Davidson</td>
<td>00010</td>
<td>UV</td>
<td>F</td>
<td>33</td>
<td>Y</td>
<td>10/17/16</td>
<td>U</td>
<td>N</td>
<td>1</td>
</tr>
<tr>
<td>Davidson</td>
<td>02458</td>
<td>TT</td>
<td>M</td>
<td>45</td>
<td>Y</td>
<td>11/01/16</td>
<td>U</td>
<td>Y</td>
<td>4</td>
</tr>
<tr>
<td>Williamson</td>
<td>54112</td>
<td>WV</td>
<td>F</td>
<td>47</td>
<td>Y</td>
<td>10/18/16</td>
<td>U</td>
<td>Y</td>
<td>2</td>
</tr>
</tbody>
</table>

### Contacts Under Investigation (HIV status unknown)

Contacts = sexual partners or needle-sharing partners

<table>
<thead>
<tr>
<th>County</th>
<th>STATENO</th>
<th>Initials</th>
<th>Sex</th>
<th>Age</th>
<th>HIV Positive?</th>
<th>HIV Diagnosis Date</th>
<th>HCV Positive?</th>
<th>IDU?</th>
<th># Named Contacts</th>
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<tr>
<td>Davidson</td>
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<td>AA</td>
<td>F</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td>Y</td>
<td>1</td>
</tr>
</tbody>
</table>
Appendix B – HIV Just in Time Training
The following training should be used to train health department staff that might not be familiar with HIV:

### Identified Populations for HIV Screening

**Encourage testing for all persons:**

1. Requesting HIV testing/counseling
2. Aged 15-65 years (one-time opt-out testing)
3. At high-risk for HIV infection, including: Men who have sex with men (MSM); Injection/intranasal drug users; Partners (sexual/needle sharing) of injection/intranasal drug users; Individuals with a sexual (oral/anal/vaginal) partner known to be HIV positive; Individuals who have exchanged sex (oral/anal/vaginal) for commodities; Individuals who have previously been diagnosed with STI; Individuals who are positive for HBV/HCV/TB; Individuals with a history of unregulated tattooing
4. Any other groups identified as part of the cluster/outbreak investigation

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**TN Department of Health**
Laboratory Markers for HIV-1 Infection

HIV Pre-test Counseling

Risk reduction counseling for all clients:

- **Do not share** any needles or other equipment to inject or snort drugs, including dollar bills, straws, needles, cooker, and filters
- **Avoid** unregulated tattoos, body piercings, or permanent cosmetics
- **Do not share** any items that may come in contact with another person’s blood (medical equipment, personal items)
- **Use condoms** consistently during all sexual activity
- **Know your status** and the status of those with whom they engage in sexual activities
HIV Post-test Counseling

Review test results (refer to slides 4 & 5 for testing algorithm and interpretation)

For HIV positive clients:
1.) Refer to provider
2.) Encourage adherence to HIV treatment regimen as prescribed
3.) Discuss relevant HIV state laws regarding disclosure of status

For HIV negative clients:
1.) Encourage high-risk* patients to talk to their provider about Pre-Exposure Prophylaxis (PrEP)

Always ask patients if they have questions or concerns
Direct to reliable sources for additional information
*see slide 1

Molecular HIV Testing
(i.e., Genotyping)

Who: For cluster investigations; will be notified by Central Office

10 ml SST (Tiger/Marble Top) Tube

Clot room temp; centrifuge within 4 hours of collection; then refrigerate

Label with 2 IDENTIFIERS AND write REDCap Outbreak # on label

Courier pickup same day; to Nashville Lab; use Red Nashville label
Appendix C – HCV Just in Time Training

The following training should be used to train health department staff that might not be familiar with HCV:

1.) Baby Boomers: Born between **1945-1965**

2.) High Risk Activities: Injection/illicit/intanasal drug use (even once); **Incarceration**; Unregulated tattoo/cosmetic application/body piercing; History of **high risk** sexual behavior; Blood transfusion or organ transplant **prior to 1992**

3.) Patients seeking **STI evaluation/services**

4.) Patients **requesting** HCV testing/counseling
**HCV Pre-Test Counseling**

- **Don’t share** needles or other equipment to inject or snort, includes dollar bills, straws, needles, cookers and filters
- **Avoid** unregulated tattoos, body piercings or permanent cosmetics
- **Don’t share** any items that may come into contact with another person’s BLOOD (razors, toothbrushes, nail clippers, diabetic equipment)
- **Use condoms** consistently during all sexual activity
- Receive both **Hepatitis A and B vaccines** to protect the liver
- **Pre-conception** counseling

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**Testing/Interpretation**

**HCV Ab NEGATIVE**: most likely not infected; assess for ongoing risk

**HCV Ab POSITIVE**: HCV RNA testing needed (TN State Lab; automatic RNA reflex testing)

**HCV Ab POSITIVE/HCV RNA NEGATIVE**: infection cleared/not currently infected; assess for ongoing risk

**HCV Ab POSITIVE/HCV RNA POSITIVE**: currently infected, evaluation & treatment needed by experienced provider; Counsel of results; Report to VHCare Navigator
HCV RNA-Positive Additional Post-Test Counseling

- Preconception counseling/contraception; reduce unintended pregnancy and mother-to-child transmission
- See your doctor regularly
- Hepatitis C is curable
- Avoid alcohol; consult a health care provider before taking any over-the-counter medication
- Refrain from donation blood, semen, organs or tissue
- Join a support group to learn more about the disease and ways to improve your health
- Always ask patients if they have questions or concerns
- Direct to reliable sources for additional information

GHOST Testing

Who: For cluster investigations; will be notified by Central Office

10 ml SST (Tiger/Marble Top) Tube
- Clot room temp, centrifuge within 4 hours of collection, then refrigerate
- Label with 2 IDENTIFIERS AND write REDCap Outbreak # on label
- Courier pickup same day, to Nashville Lab, use Red Nashville label
- Diagnosis code: Z1159 (screen for viral diseases)
- Program code: E1

LOE PTBMS: HEPC + supplemental screen; Note: No LOE for HBsAG so need paper requisition to request
Appendix D – HIV/HCV Testing and Specimen Collection and Transport Guidance

HIV Testing
HIV: The state laboratory will test for an HIV-½ antibody/antigen test followed by an HIV-1/2 antibody type differentiating immunoassay with a reflex to a HIV-1 NAT if HIV-1 is negative or indeterminate. Samples with a positive confirmatory test will be sent to CDC for HIV molecular testing.

HIV Molecular Testing
HIV sequencing data can be used to confirm if the cluster under investigation has genetically similar strains of HIV, indicating potential epidemiological links, i.e., HIV transmission networks. In the event of a cluster or an outbreak, the TDH State Laboratory, located in Nashville, TN, will transmit serum samples to CDC for HIV molecular testing.

HCV Testing
HCV: The state laboratory will test for antibody with automatic reflex to RNA. For those that are RNA positive, GHOST testing will be employed at the state laboratory.

Global Hepatitis Outbreak Surveillance Technology (GHOST)
GHOST is a CDC developed bioinformatics tool that allows for advanced molecular detection to determine and disrupt transmission networks. In the event of an outbreak, the TDH State Laboratory, located in Nashville, TN, has the capacity to conduct GHOST testing and has been trained by CDC on this technology.

Specimen Collection and Transport Guidance
The following collection, storage, and transport guidance should be followed for both HIV and HCV testing in the event of a cluster or outbreak.

Collection and Storage
1. Syringes, needles, and collection tubes should be clean, dry, and sterile to prevent contamination and hemolysis of the specimen. Vacutainer tubes (or equivalent) may be used and should have labels attached securely for patient identification.

2. Draw two 10ml red top or tiger top tubes of blood and allow it to clot at room temperature. One tube will be for HIV and HIV molecular testing and one tube will be for HBV, HCV, and GHOST testing. Ideally, blood should not be taken within 1 hour after a meal to avoid chylous serum. Identify the specimen with name of the patient immediately after collection to avoid error. Tubes must be labeled with at least two unique identifiers to be acceptable for testing (e.g. name and date of birth). Place the PTBMIS lab order label with barcode lengthwise on the specimen tube with the REDCap Outbreak # handwritten on the label and highlighted with a pink highlighter. Do not interchange labels. Labels are specific for the test ordered (e.g. do not place an HIV specimen label on the tube intended for HCV testing).

Note: If collected in a tiger-top tube, specimens must be centrifuged prior to refrigeration. Centrifuge for 15 minutes at approximately 3300 rpm. Specimens collected in a 10ml red top do not need centrifugation prior to transport to the laboratory. If 10 ml tubes are needed, please contact the state laboratory.

3. Refrigerate the specimens until time to place out for the courier. If desired, cold packs may be placed in the lockbox to keep samples cold until pickup by the courier.
Transport
1. Specimens should be sent to the laboratory by state courier at the end of the collection day. Specimens for HCV should be labeled with the red NASHVILLE courier label to ensure specimens are delivered to the correct laboratory. HIV, RPR and CT/GC specimens collected on the same patient will continue to be delivered to the appropriate regional lab for testing and should be labeled accordingly.

   **Note:** If the Nashville courier only picks up on Mondays, Wednesdays, and Fridays, then specimens can be refrigerated for up to one additional calendar day prior to pick-up.

2. All specimens should be packed with absorbent material to prevent breakage and to absorb fluid if breakage or leakage should occur.

3. Specimens sent via state courier should be shipped in mailing containers approved by the Department of Transportation and should be packaged and labeled in accordance to DOT regulations.

Appendix E - HIV/HCV Questionnaire
The following questionnaire should be utilized to interview patients in the event of a cluster or outbreak. Epidemiologist and DIS teams are recommended.
Demographic Information for Suspected HIV/HCV Outbreak

Date Completed (mm/dd/yy): ______/_____/______ Completed By: __________________________
Phone Number: (____) _______ Place of Interview: □ Clinic □ Field □ Internet □ Telephone □ Other
If other please specify: __________________________

DEMOGRAPHIC INFORMATION

REDCap Patient ID #: __________________________
First Name (P, E, N): ____________ Middle Name (P, E, N): ____________ Last Name (P, E, N): ____________
Other Name (P, E): ________________
Date of Birth (mm/dd/yy) (P, E, N): ______/_____/______ Current Age (Years): ____________
Birth Sex (P, E, N): □ Female □ Male □ Refuse to Answer □ Unknown
Current Gender (P, E): □ Female □ Male □ Transgender Male-to-Female
□ Transgender Female-to-Male □ Additional Gender Identity (please specify: ________________)
□ Refuse to Answer
Ethnicity (P, E, N): □ Hispanic □ Non-Hispanic
Race (P, E, N): □ White □ Black □ Asian □ American Indian/Alaska Native
□ Native Hawaiian or Other Pacific Islander □ Multi-Race
□ Other (please specify: ________________): □ Refuse to Answer, Unknown
Marital Status (P, E, N): □ Separated □ Married □ Divorced □ Single □ Widowed
Primary Language Spoken: __________________________
Translator Needed: □ Yes □ No
Address Type (E): □ Residential □ Bad Address □ Correctional Facility
□ Foster Home □ Homeless □ Postal □ Shelter □ Temporary
Street Address 1 (P, E, N): __________________________ Street Address 2 (P, E, N): __________________________
County (P, E, N): __________________________
What other states/countries have you lived in besides Tennessee?: __________________________
Other Locations/Hangouts (school, work, parks, neighborhoods, etc.): __________________________
Primary Phone Number (P, E, N): (____) _______ Other Phone Number (P, E, N): (____) _______
Female Patient for Suspected HIV/HCV Outbreak

First Name: ___________________________ Middle Name: ___________________________ Last Name: ___________________________
Date of Birth (mm/dd/yy): ___________________________ Date Completed (mm/dd/yy): ___________________________ REDCap Patient ID #: ___________________________ Completed By: ___________________________

PREGNANCY INFORMATION
1. Currently Pregnant (P, E, N): 
   - Yes
   - No
   - Unknown
   If yes:
     - Due Date (mm/dd/yy) (P, E, N): ___________________________
     - Receiving gynecological or obstetrical services (P, E, N): 
       - Yes
       - No
       - Unknown
     If yes, who is your provider (Name and Phone Number) (P, E, N):

2. Previously delivered live-born infants (E): 
   - Yes
   - No
   - Unknown
   If yes:
     - Number of live-born infants (E): ___________________________
     - Are you currently breastfeeding (E): 
       - Yes
       - No

BIRTH HISTORY (I)

Child One
- Child's First Name: ___________________________ Child's Last Name: ___________________________
- Child's Date of Birth (mm/dd/yy): ___________________________
- Facility Name (if child was born at home, enter “home birth”): ___________________________
- Facility Type: 
  - Inpatient
  - Outpatient
  - Other Facility (please specify): ___________________________
- Facility Street Address: ___________________________
- Facility State: ___________________________ Facility Zip Code: ___________________________ Facility City: ___________________________
- Facility County: ___________________________

Child Two
- Child's First Name: ___________________________ Child's Last Name: ___________________________
- Child's Date of Birth (mm/dd/yy): ___________________________
- Facility Name (if child was born at home, enter “home birth”): ___________________________
- Facility Type: 
  - Inpatient
  - Outpatient
  - Other Facility (please specify): ___________________________
- Facility Street Address: ___________________________
- Facility State: ___________________________ Facility Zip Code: ___________________________ Facility City: ___________________________
- Facility County: ___________________________

Child Three
- Child's First Name: ___________________________ Child's Last Name: ___________________________
- Child's Date of Birth (mm/dd/yy): ___________________________
- Facility Name (if child was born at home, enter “home birth”): ___________________________
- Facility Type: 
  - Inpatient
  - Outpatient
  - Other Facility (please specify): ___________________________
- Facility Street Address: ___________________________
- Facility State: ___________________________ Facility Zip Code: ___________________________ Facility City: ___________________________
- Facility County: ___________________________

Child Four
- Child's First Name: ___________________________ Child's Last Name: ___________________________
- Child's Date of Birth (mm/dd/yy): ___________________________
- Facility Name (if child was born at home, enter “home birth”): ___________________________
- Facility Type: 
  - Inpatient
  - Outpatient
  - Other Facility (please specify): ___________________________
- Facility Street Address: ___________________________
- Facility State: ___________________________ Facility Zip Code: ___________________________ Facility City: ___________________________
- Facility County: ___________________________
HIV/HCV Testing for Suspected HIV/HCV Outbreak

First Name: ___________________   Middle Name: _______________   Last Name: ___________________
Date of Birth (mm/dd/yy): / /   REDCap Patient ID #: _______________
Date Completed (mm/dd/yy): / /   Completed By: _______________

HIV HISTORY ( )

1. Have you had a previous HIV test:
   - Yes
   - No
   - Don’t Know
   
   If yes:
   - What was the test result of most recent test?
     - Positive
     - Negative
     - Don’t Know
   
   If positive:
   - Date of first positive HIV test (mm/dd/yy): / / 
   - In which state did you first test positive: _______________
   - Are you currently in care or treatment for HIV?
     - Yes
     - No
     - Don’t Know
   
   If yes, who is your provider? _______________
   - Are you currently taking antiretroviral (ARV) medications?
     - Yes
     - No
     - Don’t Know

HCV HISTORY ( )

1. Have you had a previous HCV test:
   - Yes
   - No
   - Don’t Know
   
   If yes:
   - What was the test result of most recent test?
     - Positive
     - Negative
     - Don’t Know
   
   If positive:
   - Date of first positive HCV test (mm/dd/yy): / / 
   - In which state did you first test positive: _______________
   - Are you currently in care or treatment for HCV?
     - Yes
     - No
     - Don’t Know
   
   If yes, who is your provider? _______________
   - Have you received HCV medications?
     - Yes
     - No
     - Don’t Know
   
   If yes, what is the name of the medication?

HIV/HCV Testing ( )

1. Rapid HIV test performed?
   - Yes
   - No
   - Don’t Know
   
   If yes, Results?
   - Positive
   - Negative
   
   Date Collected (mm/dd/yy): / / 

2. Rapid HCV test performed?
   - Yes
   - No
   - Don’t Know
   
   If yes, Results?
   - Positive
   - Negative
   
   Date Collected (mm/dd/yy): / / 

Blood drawn for (check all that apply):
- HIV
- HCV
- HBV

Date Collected (mm/dd/yy): / / 

No blood drawn today, will come in on / / (mm/dd/yy) to have blood drawn
## Sexual Behavior History for Suspected HIV/HCV Outbreak

*(Please list partners in the last year on the Contact Tracing Form)*

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name/ Middle Name/ Last Name</td>
<td></td>
</tr>
<tr>
<td>Date of Birth (mm/dd/yy)</td>
<td></td>
</tr>
<tr>
<td>Date Completed (mm/dd/yy)</td>
<td></td>
</tr>
<tr>
<td>REDCap Patient ID #</td>
<td></td>
</tr>
<tr>
<td>Completed By</td>
<td></td>
</tr>
</tbody>
</table>

### Sexual History

1. In the past year, have you had sex (vaginal, anal, oral) with (mark all that apply) *(P, E, N)*:
   - Males
   - Females
   - Transgender Persons
   - Refused
   - Don’t Know/Unknown

2. How many sexual partners have you had in the last year? ____________________ = Don’t Know/Unknown

3. In the past year, have you exchanged sex for drugs, money, or something else you needed? *(P)*:
   - Yes
   - No
   - Refused
   - Don’t Know/Unknown

4. In the past year, have you had sex because you were intoxicated or high?
   - Yes
   - No
   - Refused
   - Don’t Know/Unknown

5. In the past year, have you had a sex partner who is HIV positive?
   - Yes
   - No
   - Refused
   - Don’t Know/Unknown

6. In the past year, have you had a sex partner who uses injectable drugs?
   - Yes
   - No
   - Refused
   - Don’t Know/Unknown

7. *(If female)* In the past year, have you had a male sex partner who has sex with men?
   - Yes
   - No
   - Refused
   - Don’t Know/Unknown

8. In the past year, have you had a sex partner who has had sex with a person who uses injectable drugs?
   - Yes
   - No
   - Refused
   - Don’t Know/Unknown

9. In the past year, have you had sex with someone who exchanged sex for drugs, money, or something else you needed?:
   - Yes
   - No
   - Refused
   - Don’t Know/Unknown

10. In the past year, have you had sex with someone you didn’t know?
    - Yes
    - No
    - Refused
    - Don’t Know/Unknown

### Notes

---

Page 4
### Drug Use, Tattoo, and Incarceration History for Suspected HIV/HCV Outbreak

(Please list partners in the last year on the Contact Tracing Form)

<table>
<thead>
<tr>
<th>Drug History</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have you smoked illicit drugs (even once): (P, E, N):</td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td>- Refused</td>
</tr>
<tr>
<td>- Don't Know/Unknown</td>
</tr>
<tr>
<td>If yes (check all that apply):</td>
</tr>
<tr>
<td>- Cocaine</td>
</tr>
<tr>
<td>- Opioids</td>
</tr>
<tr>
<td>- Heroin</td>
</tr>
<tr>
<td>- Meth</td>
</tr>
<tr>
<td>- Other, please specify:</td>
</tr>
<tr>
<td>2. Have you snorted illicit drugs (even once): (P, E, N):</td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td>- Refused</td>
</tr>
<tr>
<td>- Don't Know/Unknown</td>
</tr>
<tr>
<td>If yes (check all that apply):</td>
</tr>
<tr>
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<tr>
<td>- Opioids</td>
</tr>
<tr>
<td>- Heroin</td>
</tr>
<tr>
<td>- Meth</td>
</tr>
<tr>
<td>- Other, please specify:</td>
</tr>
<tr>
<td>3. Have you injected illicit drugs (even once): (P, E, N):</td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td>- Refused</td>
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<tr>
<td>- Don’t Know/Unknown</td>
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<tr>
<td>If yes (check all that apply):</td>
</tr>
<tr>
<td>- Cocaine</td>
</tr>
<tr>
<td>- Opioids</td>
</tr>
<tr>
<td>- Heroin</td>
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<tr>
<td>- Meth</td>
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<tr>
<td>- Other, please specify:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tattoo History (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you have a tattoo:</td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td>- Refused</td>
</tr>
<tr>
<td>- Don't Know/Unknown</td>
</tr>
<tr>
<td>If yes, where was the tattooing performed (check all that apply):</td>
</tr>
<tr>
<td>- Parlor/Shop</td>
</tr>
<tr>
<td>- Correctional Facility</td>
</tr>
<tr>
<td>- Other, please specify:</td>
</tr>
<tr>
<td>2. Have you shared tattoo equipment with another person?</td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td>- Refused</td>
</tr>
<tr>
<td>- Don't Know/Unknown</td>
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</table>

<table>
<thead>
<tr>
<th>Incarceration History</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have you ever been incarcerated? (P, N):</td>
</tr>
<tr>
<td>- Yes</td>
</tr>
<tr>
<td>- No</td>
</tr>
<tr>
<td>- Refused</td>
</tr>
<tr>
<td>- Don't Know/Unknown</td>
</tr>
<tr>
<td>If yes:</td>
</tr>
<tr>
<td>In what type of facility were you incarcerated (N) (check all that apply):</td>
</tr>
<tr>
<td>- Jail</td>
</tr>
<tr>
<td>- Prison</td>
</tr>
<tr>
<td>- Juvenile Facility</td>
</tr>
<tr>
<td>- Don’t Know/Unknown</td>
</tr>
</tbody>
</table>

### Notes


Page 5
# Contact Tracing for Suspected HIV/HCV Outbreak

First Name: ___________________  Middle Name: ___________________  Last Name: ___________________

Date of Birth (mm/dd/yy): __/__/____  REDCap Patient ID #: ___________________

Date Completed (mm/dd/yy): __/__/____  Completed By: ___________________

## PARTNER ELICITATION (P, N)

<table>
<thead>
<tr>
<th>Name &amp; Nickname</th>
<th>Exposure(s)</th>
<th>Duration (specify exposure, start date, frequency, end date)</th>
<th>Phone Number</th>
<th>Address</th>
<th>Email Address</th>
<th>Description</th>
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<td>P1 = sex partner</td>
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<td>P2 = needle sharing partner</td>
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<td>P3 = both sex and needles</td>
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</table>
Non-Partner Contact Tracing for Suspected HIV/HCV Outbreak

<table>
<thead>
<tr>
<th>First Name:</th>
<th>Middle Name:</th>
<th>Last Name:</th>
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</table>

Date of Birth (mm/dd/yy): __/__/____    REDCap Patient ID #: ____________
Date Completed (mm/dd/yy): __/__/____    Completed By: ________________

CLUSTERING
Who else would benefit from testing? Please provide contact information.

<table>
<thead>
<tr>
<th>Contact Information</th>
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<th>Contact Information</th>
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<tr>
<th>Contact Information</th>
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</thead>
</table>

DRUG USE & PURCHASING
Where have you used or purchased drugs in the past year? Please be specific.

<table>
<thead>
<tr>
<th>Drug Use or Purchase</th>
<th></th>
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</table>

<table>
<thead>
<tr>
<th>Drug Use or Purchase</th>
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<tr>
<th>Drug Use or Purchase</th>
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</thead>
</table>

Page 10
DRUG USE & PURCHASING CONTINUED

Where have people in your area used drugs in the past year? Please be specific.

NOTES
Appendix F - Call Agenda and Situation Report Templates

Call Agenda Template
This document should be completed by SHOC Planning and circulated to all invited parties at least one business day prior to a scheduled call.

HIV/HCV Cluster Investigation Call (REDCap Outbreak #)
Call Date and Time (CST/EST)

- Roll Call
- TDH Lab Update
- Regional Epi Updates (see Situation Report for reference)
- Central Office Updates
- Discussion: Strategy for closing this investigation

Next Call:  Call Date and Time (CST/EST)
Call in number: | Passcode:

Contact Info:
Lab

Region(s)

Central Office

Situation Report Template
This document should be completed by regional staff and sent to SHOC Planning at least one business day prior to a scheduled call.

Situation Report
HIV/HCV Cluster Investigation – Region Name
(REDCap Outbreak Investigation #)

Date Updated:

Notification
On XX/XX/XXXX, The Tennessee Department of Health was notified of a possible increase in coinfections among HIV-positive persons in X. Subsequent investigation demonstrated X new HIV diagnoses among IDU who named each other as contacts (IDU). This prompted an investigation and increased surveillance into a possible cluster of HIV/HCV in X.
Current Situation (*Table 1*)

<table>
<thead>
<tr>
<th>Region X</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td># cases diagnosed since [fill in date]</td>
<td></td>
</tr>
<tr>
<td># cases interviewed w/ OBRF</td>
<td></td>
</tr>
<tr>
<td># cases still needing interview with OBRF</td>
<td></td>
</tr>
<tr>
<td># IDU cases</td>
<td></td>
</tr>
<tr>
<td># cases interviewed w/ OBRF</td>
<td></td>
</tr>
<tr>
<td># cases still needing interview with OBRF</td>
<td></td>
</tr>
<tr>
<td># cases that are IDUs*</td>
<td></td>
</tr>
<tr>
<td># contacts of IDU* cases</td>
<td></td>
</tr>
<tr>
<td># contacts of IDU* cases interviewed w/ OBRF</td>
<td></td>
</tr>
<tr>
<td># contacts of IDU* cases needing interview with OBRF</td>
<td></td>
</tr>
<tr>
<td># contacts IDU* cases tested for HIV</td>
<td></td>
</tr>
<tr>
<td># contacts IDU* cases = new HIV+ (cases)</td>
<td></td>
</tr>
<tr>
<td># contacts IDU* cases = prior HIV+</td>
<td></td>
</tr>
<tr>
<td># contacts IDU* cases = negative</td>
<td></td>
</tr>
<tr>
<td># contacts IDU* cases = pending</td>
<td></td>
</tr>
<tr>
<td># contacts IDU* cases not yet tested for HIV</td>
<td></td>
</tr>
</tbody>
</table>

*IDU in this table represents IDU + IDU/MSM; Highlighted areas represent priority tasks.

Epidemiology Curve

Note: Red = IDU, Yellow = IDU/MSM, Blue = Other or NIR, Black = Unknown
**REDCap Completeness & Laboratory Results (Table 2)**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Region X (n (%))</th>
<th>Total n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total HIV+ Cases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interviewed with OBR Form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reported IDU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tested for HCV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Contacts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interviewed with OBR Form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reported IDU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tested for HIV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior Positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tested for HCV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pending</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Public Health Action**

(Outreach events / messaging / work to find contacts / etc.)

**Action Plan**

- Train all DIS in phlebotomy
- Train HD staff for pre/post-test HIV counseling
- Investigate harm reduction avenues, non-SEP
- Assure we have Spanish interpreter available
- Update county and city mayors

**Cluster Case Definitions**

**HIV Case Definitions**

**Confirmed Case:**
A person with:

- laboratory confirmed HIV infection, newly diagnosed after [fill in date] (by date of specimen collection) – AND –
- who either resided in Region X OR – was named by another case as a syringe-sharing or sexual partner
Probable Case:

A person with:

- rapid positive HIV test after [fill in date] (by date of specimen collection) – AND –
- who either resided in Region X – OR – was named by another case as a syringe-sharing or sexual partner

Suspect Case:

A person with:

- signs and symptoms of acute HIV infection (fever, malaise, lymphadenopathy, pharyngitis, headache, night sweats, myalgia or rash) after [fill in date of specimen collection] – AND –
- who either resided in Region X – OR – was named by another case as a syringe-sharing or sexual partner
Social Network Analysis

TN17-209 HIV/HCV Cluster SNA
updated 06-20-2017
Appendix G – Additional Resources

CDC HIV Case Definition

Revised Surveillance Case Definition
Section 1: Criteria for a Confirmed Case

Criteria for a confirmed case can be met by either laboratory evidence or clinical evidence, as described below. Laboratory evidence is preferred over clinical evidence.

1.1: Persons Aged ≥18 Months and Children Aged <18 Months whose Mothers were Not Infected
1.1.1: Laboratory Evidence

Laboratory criteria require reporting of the date of the specimen collection for positive test results in multitet algorithms or stand-alone virologic tests and enough information about the tests to determine that they met any of the following criteria:

- A multitet algorithm consisting of
  - A positive (reactive) result from an initial HIV antibody or combination antigen/antibody test, and
  - An accompanying or subsequent positive result from a supplemental HIV test different from the initial test (8).

The initial HIV antibody or antigen/antibody test and the supplemental HIV test that is used to verify the result from the initial test can be of any type used as an aid to diagnose HIV infection. For surveillance purposes, supplemental tests can include some not approved by the Food and Drug Administration (FDA) for diagnosis (e.g., HIV-1 viral load test, HIV-2 Western blot/immunoblot antibody test, and HIV-2 NAT). However, the initial and supplemental tests must be “orthogonal” (i.e., have different antigenic constituents or use different principles) to minimize the possibility of concurrent nonspecific reactivity. Because the antigenic constituents and test principles are proprietary information that might not be publicly available for some tests, tests will be assumed to be orthogonal if they are of different types. For example:

- One test is a combination antigen/antibody test and the other an antibody-only test.
- One test is an antibody test and the other a NAT.

- One test is a rapid immunoassay (a single-use analytical device that produces results in <30 minutes) and the other a conventional immunoassay.
- One test is able to differentiate between HIV-1 and HIV-2 antibodies and the other is not.

Tests also will be assumed to be orthogonal if they are of the same type (e.g., two conventional immunoassays) but made by different manufacturers. The type of HIV antibody test that verifies the initial test might be one formerly used only as an initial test (e.g., conventional or rapid immunoassay, HIV-1/2 type-differentiating immunoassay), or it might be one traditionally used as a supplemental test for confirmation (e.g., Western blot, immunofluorescence assay).

- A positive result of a multitet HIV antibody algorithm from which only the final result was reported, including a single positive result on a test used only as a supplemental test (e.g., HIV Western blot, immunofluorescence assay) or on a test that might be used as either an initial test or a supplemental test (e.g., HIV-1/2 type-differentiating rapid antibody immunoassay) when it might reasonably be assumed to have been used as a supplemental test (e.g., because the algorithm customarily used by the reporting laboratory is known).

- A positive result or report of a detectable quantity (i.e., within the established limits of the laboratory test) from any of the following HIV virologic (i.e., nonantibody) tests:
  - Qualitative HIV NAT (DNA or RNA)
  - Quantitative HIV NAT (viral load assay)
  - HIV-1 p24 antigen test
  - HIV isolation (viral culture) or
  - HIV nucleotide sequence (genotype).

1.1.2: Clinical (Nonlaboratory) Evidence

Clinical criteria for a confirmed case (i.e., a “physician-documented” diagnosis for which the surveillance staff have not found sufficient laboratory evidence described above) are met by the combination of:

- A note in a medical record by a physician or other qualified medical-care provider that states that the patient has HIV infection, and
- One or both of the following:
  - The laboratory criteria for a case were met based on tests done after the physician’s note was written (validating the note retrospectively).
  - Presumptive evidence of HIV infection (e.g., receipt of HIV antiretroviral therapy or prophylaxis for an opportunistic infection), an otherwise unexplained low CD4+ T-lymphocyte count, or an otherwise unexplained diagnosis of opportunistic illness (Appendix).

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8 [https://www.cdc.gov/mmwr/pdf/rr/rr6303.pdf](https://www.cdc.gov/mmwr/pdf/rr/rr6303.pdf)
HIV Testing Sequence

New CDC Recommendations for HIV Testing in Laboratories

A step-by-step account of the approach

CDC's new recommendations for HIV testing in laboratories capitalize on the latest available technologies to help diagnose HIV infections earlier—up to 3-4 weeks sooner—than the previous testing approach. Early diagnosis is critical since many new infections are transmitted by people in the earliest ("acute") stage of infection.

By putting the latest testing technology to work in laboratories across the United States, we can help address a critical gap in the nation’s HIV prevention efforts.

Step 1: “Fourth generation” HIV Test
Detecting HIV sooner

Detects HIV in the blood earlier than previously recommended antibody tests by identifying the HIV-1 p24 antigen, a viral protein which appears in the blood sooner than antibodies.

Step 2: HIV-1/HIV-2 Antibody Differentiation Immunoassay
Diagnosing HIV-1 vs. HIV-2

Produces results faster than the previously recommended Western Blot.

Distinguishes between HIV-1 and HIV-2, which the previously recommended Western Blot cannot do—this distinction has important treatment implications for a patient.

Step 3: Nucleic Acid Test (NAT)
Acute HIV-1 infection or "false positive?"

Ensures accurate detection of early infection or indicates a false positive from the fourth-generation test.

Interpret Test Results as HIV-1 or HIV-2

Negative or Indeterminate

Positive

This graphic is designed to illustrate key concepts of the new testing approach in laboratories. For more detail, please see the full guidelines here: https://www.cdc.gov/nchhstp/newsroom/docs/2014/hiv-testing-labs-flowchart.pdf

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

www.cdc.gov/nchhstp/newsroom

JUNE 2014

2016 HCV CDC/CSTE Case Definitions

Clinical Criteria
An illness with discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), AND
   a) jaundice
OR
   b) peak elevated serum alanine aminotransferase (ALT) level > 200 IU/L during the period of acute illness.

Laboratory Criteria
- A positive test for antibodies to hepatitis C virus (anti-HCV)
- Hepatitis c virus detection test:
  - Nucleic acid test (NAT) for HCV RNA positive (including quantitative, qualitative or genotyping testing)
  - A positive test indicating the presence of hepatitis C viral antigen(s) (HCV antigen)*

Case Classification

Acute, confirmed: A case that meets clinical criteria and has a positive hepatitis C virus detection test (HCV NAT or HCV antigen)
OR
A documented negative HCV antibody, HCV antigen or NAT laboratory test result followed within 12 months by a positive result of any of these tests (test conversion)

Acute, probable: A case that meets clinical criteria and has a positive anti-HCV antibody test, but has no reports of a positive HCV NAT or positive HCV antigen tests AND
Does not have test conversion within 12 months of has no report of test

Chronic, confirmed: A case that does not meet clinical criteria or has no report of clinical criteria
AND
Does not have test conversion within 12 months or has no report of test conversion
AND
Has a positive HCV NAT or HCV antigen test

Chronic, probable: A case that does not meet clinical criteria or has no report of clinical criteria
AND
Does not have test conversion within 12 months or has no report of test conversion
AND

Has a positive anti-HCV antibody test, but no report of a positive HCV NAT or positive HCV antigen test

**HCV 2x2 Case Classification Table**

<table>
<thead>
<tr>
<th>Symptom(s) plus either a) jaundice or b) ALT &gt;200 IU/L</th>
<th>No or Unknown</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV Ab(+): only</td>
<td>Chronic, Probable</td>
<td>Acute, Probable</td>
</tr>
<tr>
<td>HCV NAT(+): or HCV Ag(+)</td>
<td>Chronic, Confirmed</td>
<td>Acute, Confirmed</td>
</tr>
</tbody>
</table>

**Acute**

- Seroconversion: (-) HCV Ab, HCV Ag, or HCV NAT followed by a (+) of any of these within 12 months (see test conversion table below) = Acute, Confirmed

**Test Conversion within 12 Months Combinations**

<table>
<thead>
<tr>
<th>First Result</th>
<th>Second Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>(-) HCV Ab</td>
<td>(+) HCV Ab, (+) HCV Ag or (+) HCV NAT</td>
</tr>
<tr>
<td>(-) HCV Ag</td>
<td>(+) HCV Ag or (+) HCV NAT</td>
</tr>
<tr>
<td>(-) HCV NAT</td>
<td>(+) HCV Ag or (+) HCV NAT</td>
</tr>
</tbody>
</table>

**Chronic:**

- (+) HCV Ab, (-) RNA, and no other labs on file or the same results previously = Chronic, Probable
- (+) HCV Ab, (-) RNA, and prior (+) RNA = Chronic, Confirmed
- (-) HCV Ab, standalone = Chronic, Not a Case
- (-) HCV RNA, standalone = Chronic, Not a Case
HCV Testing Sequence

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

Screening: Tests for presence of HCV Antibody test (serum).

Confirmatory: Nucleic acid tests that looks for presence of the virus by the presence of viral RNA (quantitative or qualitative). These can include: polymerase chain reaction (PCR), genotyping, or antigen*.

*To date, the HCV antigen test is not available in Tennessee

HIV Resources

- CDC – HIV Fact Sheets
- CDC - HIV Surveillance Reports
  http://www.cdc.gov/hiv/library/reports/surveillance/

HCV Resources

- GHOST
- CDC – Viral Hepatitis – Hepatitis C Information
  http://www.cdc.gov/hepatitis/hcv/index.htm
- CDC – Testing Recommendations for Hepatitis C Virus Infection
  http://www.cdc.gov/hepatitis/hcv/guidelinesc.htm
- CDC – Hepatitis C Fact Sheets
  http://www.cdc.gov/hepatitis/hcv/cfaq.htm
- CDC – The ABC’s of Hepatitis
  http://www.cdc.gov/hepatitis/Resources/Professionals/PDFs/ABCTable.pdf
- University of Washington - Hepatitis C Online Course
  http://www.hepatitisc.uw.edu/alternate

HIV/HCV Co-Infection Resources

- HIV and Hepatitis – Hepatitis C
  http://www.hivandhepatitis.com/hepatitis-c

Acknowledgements
The Tennessee Department of Health would like to recognize the following employees for their contributions to this document and/or associated activities: Lindsey Sizemore, Julie Shaffner, Samantha Mathieson, Rendi Murphree, Meredith Brantley, Mary-Margaret Fill, Shanell McGoy, Corinne Davis, Kim Truss, Jennifer Black, Michael Rickles, Allison Sanders, and Carolyn Wester.